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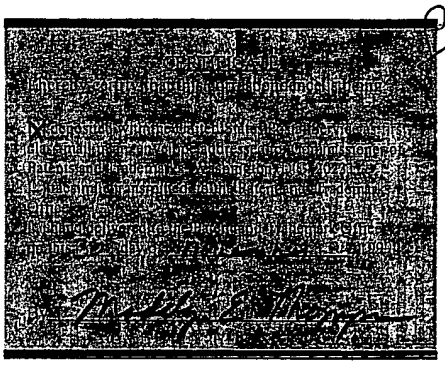
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:) Art Unit: 3736
)
Qi-Bin Bao et al.) Atty. Docket 32355.22
Serial No. 09/086,848)
) Examiner: H. Phan
Filed: May 29, 1998)
)
For: IMPLANTABLE TISSUE)
REPAIR DEVICE)

Hon. Commissioner of
Patents and Trademarks
Washington, D.C. 20231



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AMENDMENT

This is in response to the Office Action mailed August 31, 1999, the unextended period for response to which is set to expire November 30, 1999.

In the Specification

Please amend the specification as follows:

Page 7, line 26, delete "annulus 2" and insert therefore -- annulus 3 --.

In the Claims

Kindly amend the claims as follows:

Please amend claims 1, 3, and 13 in the following manner (where insertions are underlined and deletions placed in brackets):

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01 FC:203 45.00 OP
02 FC:202 39.00 OP

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1. (once amended) A device for sealing a biological aperture *in situ*, the device comprising a porous, expandable material adapted to be sealably positioned within the biological aperture and to permit natural tissue ingrowth into the device.

~~3.~~ (once amended) A device according to claim 1 wherein the material is [porous and] adapted to be delivered to and positioned within the aperture, in conformity with the dimensions of the aperture, using minimally invasive techniques.

13. (once amended) A method according to claim ~~11~~ wherein the material is [porous and] adapted to be delivered to and positioned within the aperture, in conformity with the dimensions of the aperture, using minimally invasive techniques.

Add new claims 25-29 as follows:

~~25.~~ (new) A device according to claim 1 wherein the aperture is provided in the form of an orifice, hole, cleft, or tear in a biological tissue.

26. (new) A device according to claim 1wherein the bioactive agent is selected from the group consisting of growth factors, angiogenic factors and immune system suppressors.

27. (new) A device according to claim 26 wherein the bioactive agent is a growth factor comprising a fibroblast growth factor.

~~28.~~ (new) A device for sealing a biological aperture *in situ*, the device comprising a porous, expandable material adapted to be sealably positioned within a biological aperture and to permit natural tissue ingrowth into the device, wherein the aperture is provided in the annulus of an intervertebral disc, the material comprises poly (vinyl alcohol), and the device is adapted to be delivered to and positioned within the aperture, in conformity with the dimensions of the aperture, using minimally invasive techniques.

29. (new) A device according to claim 28 wherein the aperture is in the annulus of an intervertebral disc, and the device is provided in a configuration selected from the group consisting of cylindrical plugs, tubular forms, and elongated, curved forms.

Remarks

Claims 1, 3 and 13 have been amended and claims 25-29 have been added, antecedent basis for the added claims existing throughout the specification, e.g., at page 4, lines 1-3 (with respect to aperture shapes), and at page 13, line 29 to page 14, line 11 (with respect to bioactive agents). Upon entry of this Amendment claims 1-29 will be pending and in condition for allowance. Accompanying this Amendment is a Supplemental Information Disclosure Statement listing references recently cited in the course of Applicant's corresponding PCT application.

The Examiner's comments regarding the Drawing are appreciated. The specification has been amended above in order to uniformly refer to the disc itself as reference number 2, and to the annular portion thereof as reference number 3.

The objection under Section 112 is rendered moot by the above editorial amendment of claim 1.

The rejections under Section 102 and 103 are each respectfully traversed. To the extent each rejection is based on Kuslich '679 as either the sole, or primary, reference, they will be considered together.

As perhaps a preliminary matter, there appears to be a fundamental misunderstanding as to the *overall* relevance of Kuslich '679 method and device to the method and device of the present invention. Kuslich '679 is concerned largely with the use of a composite product (fabric bag and graft medium) to fill a *cavity* formed within the nucleus of an intervertebral disc. As an ancillary matter, the reference includes an optional approach for also providing a *patch over* the annular aperture that is formed to provide access to that cavity (e.g., as shown in and described with respect to Fig. 47 therein). The annular patch, in turn, is formed by a method that includes the use of a punch 122 to cut out an opening sufficient to expose bleeding bone, followed by the placement and attachment of a multi-layer patch 120 by means of staples 126.

The present invention, in contrast, is instead concerned with sealing (not *covering*) apertures within the body, and only secondarily, if at all, with filling internal cavities such as those found within the disc nucleus. As such, the device of the present invention seems more properly compared with the annular punch and patch described in Kuslich '679, than with the fabric bag and medium composite itself. Based on *any* such comparison, however, the device and method of the present invention, particularly as amended above, are far more dissimilar to the teachings of Kuslich than they are similar.

In a particularly preferred embodiment, for instance, the present invention provides a porous, expandable polyvinyl alcohol sponge that can be compressed and *inserted into* a biological aperture, such as an aperture in a disc annulus, in order to seal the aperture, and to permit (if not encourage) long term soft tissue ingrowth. Claims 25-29 have been added in order to provide further combinations of features and/or to focus on several further differences between the present approach and the cited art. These include a preferred group of apertures amenable to being sealed in this fashion (claim 25), and a preferred group of bioactive agents (claims 26-27).

The rejections under Section 103, and various secondary references cited therein, add nothing to remedy the many flaws described above with respect to Kuslich '679. McKay, for instance, merely describes the use of BMP to promote *bone ingrowth* into a spine fusion cage. It fails entirely to teach or suggest a device of the present invention, nor in turn, the sealing of any aperture or the use of an agent to promote *soft tissue ingrowth* into a porous device as presently described.

The cited Bao reference (as well as the various Bao references included in the accompanying Supplemental Information Disclosure Statement), generally relate to the use of rubber-like polyvinyl alcohol *hydrogels*, as opposed to *sponges*. As with Kuslich '679, these Bao references are again concerned with replacing some or all of the disc itself, as opposed to merely sealing biological apertures. In turn, the various Bao references would tend to rely on conventional approaches for whatever annular repair steps may be added. The approach of the present invention, therefore, can be seen as an improvement that can be adapted for use with most, if not all, prior disc repair procedures, including those of Kuslich '679 and the Bao references.

The remaining secondary references are even less relevant. Scarborough et al. appears to be cited for its mere mention of a cylindrical device, albeit in a context totally unrelated to that of the present invention. Kuslich '307, in turn, is cited for its mention of the use of a cannula to deliver various elements of the system described therein, though again, in a manner quite unrelated to the methods and materials presently claimed. Put simply, there is certainly nothing in either these secondary references themselves, nor in Kuslich '697, to suggest their combination at all, let alone in a manner formed solely in hindsight and presently set forth in the Office Action.

Nor do any of the newly cited references appear to alter the conclusions set forth above. The European application of Rutkow, et al., for instance, describes an implantable *fabric* plug for use in such applications as sealing abdominal hernias. The reference describes the manner in which a porous surgical mesh fabric can be hot molded into a form that permits it to be compressed, formed into its unique pleated shape, and confined within a narrow opening in the muscle. The resulting prosthesis is quite distinct from a preferred device of the present invention, e.g., in which a cylindrical, sponge-like material is compressed and inserted into a generallly smaller aperture, such as one formed in the annulus of an intervertebral disc.

In view of the above remarks, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all rejections is respectfully requested.

Respectfully submitted,

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